REMARKS

Claims 1-8, 14-18, and 23-35, are pending in the present application. Claim 34 has been amended to correct the deficiency of a period at the end of the sentence. Claim 35 has been added; support for new claim 35 can be found throughout the specification as filed, for example, at lines 18-20 of page 4. Applicants submit that no new matter has been added by amendment. Applicants reserve the right to pursue any canceled subject matter in a future application. Issues raised in the Advisory Action are addressed in the order they were raised by the Examiner.

1. Applicants acknowledge that the amendment filed on April 11, 2003, has been entered.

2. Claims 1, 3-6, 14, and 16 and 23-24 are asserted as allegedly being unpatentable under 35 USC §103(a) over Chan in view of McLaughlin and Tadler *et al.* for the reasons of record. Applicants respectfully traverse this rejection for the reasons of record and for the reasons set forth herein.

The Examiner maintains that "applicants are alleging that the references fail to show certain features of applicant's invention, however, the feature upon which applicants are relying fail to be recited in the rejected claims. Limitations from the specification are not read into the claims".

Applicants agree with the Examiner that limitations from the specification are not read into the claims; however, the Federal Circuit has clearly stated that the claims are read in light of the disclosure of the specification. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989) (MPEP 2173.05(a)). In this case, the cited art fails to disclose binding agents that are capable of detecting clinically relevant amounts of bacteria, thus, the cited art does not anticipate or render obvious this feature. Furthermore, this feature is explicitly recited in the claims.

The Examiner further argues that a "reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments, contrary to applicants arguments". The Examiner's position appears to be that the claims do not require "that the binding agents to detect all of the gram-positive bacteria or even an entire class of microorganisms".

Again, Applicants disagree for the reasons of record and for the reasons set forth herein. Applicants maintain that the cited art fails to teach a method of screening for clinically relevant amounts of bacteria in blood or blood products as required by the claims. Nor do the references disclose any non-preferred embodiments which teach or suggest the invention as claimed. Applicants assert that although the claims do not require the detection of all of the gram-positive bacteria or even an entire class of microorganisms, the claims do require a method of screening for a clinically relevant amount of bacteria, wherein if the blood is found to be free of a clinically relevant amount of bacteria, it is safe for transfer to a recipient, a concept which is neither taught or suggested by any of Chan, McLaughlin and Tadler et al., either alone, or in combination.

The Examiner also argues that a "known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use" In re Gurley, 27 F.3d 551,554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

First, Applicants contend that the Examiner has failed to show that binding agents described in the prior art would be effective in detecting clinically relevant amounts of bacteria in blood or blood products as is required by the claims. The binding agents of the instant claims are not taught or suggested by the cited art, thus they cannot be considered as inferior products. Further, the instant claims require that blood or blood products are screened for a clinically relevant amount of bacteria, a purpose which is neither taught or suggested by Chan, McLaughlin, and/or Tadler et al. A prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the applicant". Gurley, at 1132. It is Applicants' position that one of ordinary skill wishing to develop a blood screening test for detecting clinically relevant amounts of bacteria to render the blood safe for transfusion would be discouraged from following the teachings of the references. In addition, Applicants have provided a substantial showing that one of ordinary skill in the art at the time the application was filed would not have believed that an immunoassay could be successfully used for blood screening or have a reasonable expectation of success in combining the teachings of the cited art.

The Examiner argues that the instant claims "only require that a bacterial antigen is detected, not each and every gram-negative and gram-positive bacterial antigen be detected".

Applicants respectfully assert that the difference is that binding agents must recognize a clinically-relevant amount of bacteria, and further, that they recognize a bacterial antigen that is present on the surface of gram-negative and gram-positive bacteria. Thus, the binding agents are pan-generic in that they would recognize bacteria across the genera of gram-negative bacteria or the genera of gram-positive bacteria.

Finally, the Examiner states that "Applicants argue that the use of the method has patentable weight, however, the functional limitation of the instant claims does not result in a structural difference. The prior art structure is capable of performing the intended use, thus it meets the claim".

Applicants respectfully traverse these statements. First, the Examiner has not shown that the prior art structures (binding agents) are capable of performing the intended use – i.e., screening blood and blood products for clinically relevant amounts of bacteria. Moreover, Applicants request the Examiner point to case law supporting the proposition that in a method claim a functional limitation that does not result in a structural difference it is not given patentable weight.

Accordingly, for the reasons of record and those set forth herein, reconsideration and withdrawal of this rejection is respectfully requested.

3. Claims 2 and 15 are asserted as allegedly being unpatentable over Chan, McLaughlin and Tadler et al., as applied to claims 1 and 14 above, and further in view of Chang et al. for reasons of record. Applicants respectfully traverse this rejection.

The Examiner states that the rejection is maintained for the reasons of record because "obviousness can only be established by combining or modifying the teachings of the prior art to produce one would have a reasonable expectation of success" (*sic*).

Applicants have provided several non-patent literature references indicating that those of skill in the art would not have a reasonable expectation of success of combining the cited art

because many attempts at producing a comprehensive assay as claimed over the past ten years have failed, thus there has been a long-felt need for a successful immunoassay as currently claimed. Nor do the Chan, McLaughlin, and Tadler et al. references provide any motivation to develop a method of screening for a clinically relevant amount of bacteria in blood or blood products as currently claimed.

Applicant reiterate that Chang is directed to the safety of transfer of modified hemoglobin blood substitutes (see column 4 at lines 10-30), not to a method of screening blood/blood product for clinically bacteria and found to be free of gram positive and gram negative bacteria for transfusions, nor is it even directed to the detection of clinically relevant amounts of bacteria at all.

Applicants respectfully request reconsideration and withdrawal of the rejection.

4. Claim 7 is asserted as allegedly being unpatentable over Chan (EP 461,462) in view of Tadler et al. (*J. of Clin. Lab. Anal.* 1989; 3: 21-25) under 35 USC 103(a). Applicants respectfully traverse this rejection.

The Examiner maintains that one of ordinary skill in the art would have a reasonable expectation of success in combining the teachings of Chan and Tadler et al. for the reasons of record.

It is Applicants' position for the reasons of record and those set forth above that one of ordinary skill in the art at the time the application was filed would not have had a reasonable expectation of success of arriving at the claimed invention by combining the teachings of Chan and Tadler et al. due to the overwhelming evidence that attempts to create a method for screening blood and blood products for clinically relevant amounts of bacteria throughout the 1990's had consistently failed. Thus, one of ordinary skill in the art at the time the application was filed would not have a reasonable expectation of success that producing the method as currently claimed would be a viable endeavor.

Applicants respectfully request reconsideration and withdrawal of the rejection.

7. Claims 8 and 18 are asserted as being unpatentable over Chan in view of McLaughlin for the reasons of record. Applicants respectfully traverse this rejection.

The Examiner maintains that one of ordinary sill in the art would have a reasonable expectation of success in combining the teachings of Chan and McLaughlin for the reasons of record.

Applicant's rebuttal with respect to the Chan and McLaughlin references have been discussed in the record and *supra*. As discussed above, the skilled artisan would not be motivated to modify Chan's immunoassay by using McLaughlin's antibodies because Chan is directed to a diagnostic method requiring specificity in the antibodies for the infectious agents to be detected. Therefore, it is unlikely that the skilled artisan would modify the Chan method; furthermore it is unlikely that the skilled artisan would select the McLaughlin antibodies for a screening method to detect clinically relevant amounts of bacteria in view of the teachings of the McLaughlin reference when taken as a whole.

It is Applicants' position for the reasons of record and those set forth above that one of ordinary skill in the art at the time the application was filed would not have had a reasonable expectation of success of arriving at the claimed invention by combining the teachings of Chan and McLaughlin due to the overwhelming evidence presented by Applicants that attempts to create a method for screening blood and blood products for clinically relevant amounts of bacteria throughout the 1990's had consistently failed. Thus, one of ordinary skill in the art at the time the application was filed would not have a reasonable expectation of success that producing the method as currently claimed would be a viable endeavor based on the teachings of Chan and McLaughlin.

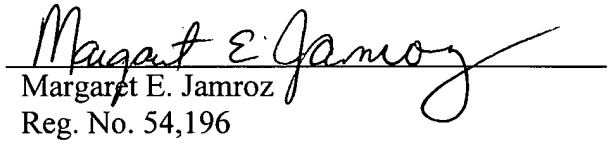
Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945.**

Respectfully Submitted,

Date: August 11, 2003



Margaret E. Jamroz
Reg. No. 54,196

Customer No: 28120
Docketing Specialist
Ropes & Gray, LLP
One International Place
Boston, MA 02110
Phone: 617-951-7000
Fax: 617-951-7050